DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, Federal Y2K Biomedical Equipment Clearinghouse
Additional Information Request Form – Products With Date-Related Problem – FORM FDA 3469

Form approved: OMB No. 0910-0417
Expiration Date: May 31, 2000
See OMB Statement on reverse

Please verify and correct, or provide any missing information and return as indicated on the instruction page.
For detailed instructions, please refer to the appropriate line number on the **BACK** of this form.

Line #	Manufacturer Information	
1.	Manufacturer Name	
2.	Division *(see instructions on the back of this form)*	
3.	Enter Your FDA Assigned Owner/Operator Number	
	Submitter/Contact Information	
4.	Submitter's Name *(First and Last)*	
5.	Submitter's Street Address	
6.	Submitter's City, State/Province and Postal Code	
7.	Submitter's Country	
8.	Submitter's Telephone	
9.	Submitter's Fax	
10.	Submitter's Email	
11.	Y2K Contact's Name *(First and Last)*	
12.	Y2K Contact's Street Address	
13.	Y2K Contact's City, State/Province and Postal Code	
14.	Y2K Contact's Country	
15.	Y2K Contact's Telephone	
16.	Y2K Contact's Fax	
17.	Y2K Contact's Email	
	Y2K Status Information	
18.	Our records indicate that your company's current Y2K status is:	**PRODUCTS WITH DATE-RELATED PROBLEM** • Please refer to the attached **Product Problem – FORM FDA 3469A** to verify and correct, or provide any missing information.
19.	Does this status reflect all products that might still be in use? *(This includes all discontinued and obsolete products that might still be in use.)*	☐ **YES** ☐ **NO** *(If NO, please report any additional products with problems on the blank **Product Problem – FORM FDA 3469A** provided with this correspondence.)*
	Additional Information	
20.	*(Please provide any additional information that would be helpful in the understanding of your company's or products' Y2K status.)*	

INFORMATION CURRENT AS OF 2/24/2000

Federal Y2K Biomedical Equipment Clearinghouse
Instructions – FORM FDA 3469

This form has been filled-in with the information your company has provided, if applicable. Please verify and correct, or provide any missing information and return as indicated on the instruction page.

If you have questions about completing this form or the Federal Y2K Biomedical Equipment Clearinghouse please call 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday, Eastern Time or Email the Y2K Clearinghouse at y2kstatus@bah.com. You may also fax your completed forms to 1-301-881-1848.

Line Number Key

Manufacturer Information	
1. Manufacturer Name	Name of the Manufacturer submitting the product information.
2. Division	Name of the Division, if this report is for ONE specific division. Complete ONE form for each division that manufactures biomedical equipment. Please leave blank if you are reporting for the entire company.
3. Enter Your FDA Assigned Owner/Operator Number	If the Manufacturer submitting Y2K status information is FDA regulated, please enter your FDA assigned Owner/Operator Number.
Submitter/Contact Information	
4. Submitter Name *(First and Last)*	First and Last Name of the person submitting the information for the manufacturer.
5. Submitter's Street Address	Street address of the submitter.
6. Submitter's City, State/Province, and Postal Code	City, State/Province, and Postal Code of the submitter.
7. Submitter's Country	Country location of the submitter.
8. Submitter's Telephone	Telephone number of the submitter.
9. Submitter's Fax	Fax number of the submitter.
10. Submitter's Email	Email address of the submitter.
11. Y2K Contact's Name *(First and Last)*	First and Last Name of the Y2K contact for the manufacturer.
12. Y2K Contact's Street Address	Street address of the Y2K contact.
13. Y2K Contact's City, State/Province, and Postal Code	City, State/Province and Postal Code of the Y2K contact.
14. Y2K Contact's Country	Country location of the Y2K contact.
15. Y2K Contact's Telephone	Telephone number of the Y2K contact.
16. Y2K Contact's Fax	Fax number of the Y2K contact.
17. Y2K Contact's Email	Email address of the Y2K contact.
Y2K Status Information	
18. Our records indicate that your company's current Y2K status is:	Confirm that the submission type identified is correct: ***Products With Date-Related Problem*** – Manufacturer reports specific products with date-related problems, and how the problems will be resolved. Submission of information is to be made only for products with date-related problems, including minor problems or for products that are obsolete. *(Complete a **Product Problem – FORM FDA 3469A** for each product that has a date-related problem.)*
19. Does this status reflect all products that might still be in use? *(This includes all discontinued and obsolete products that might still be in use)*	Does the Y2K submission type listed in line 18 reflect all products that might still be in use? This includes all discontinued and obsolete products. If NO, please provide the appropriate information on the applicable form(s) provided in this mailing for those not previously reported.
Additional Information	
20. Additional Information	Provide any additional information that may clarify any questions regarding your company's or products' Y2K status.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, search existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Year 2000 Coordinator (HFZ-Y2K)
Center for Devices and Radiological Health, FDA
9200 Corporate Boulevard
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

YEAR 2000 READINESS DISCLOSURE

Instructions – FORM FDA 3469 (2/2000)